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Per-Ola Freskgard

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EXAMINER

BABIC, CHRISTOPHER M

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1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,056	Applicant(s) FRESKGARD ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-24 is/are rejected.
- 7) ☒ Claim(s) 1-7 and 11-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-7 and 11-21, in the reply filed on June 2, 2008 is acknowledged. The traversal is on the ground(s) that that the claims recited in groups II and III have been amended to depend from newly added group I claim 22, and the claims of group I are allowable over the teachings of Szostak. This is not found persuasive because, as presented below, the claims recited in group I are not in condition for allowance. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 13. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 1-7 and 11-24 are objected to because of the following informalities:

a) The word "hybridised" recited in claims 1, 7, 15, 18, and 21 should be spelled "hybridized" to provide for appropriate spelling.

b) The word "codes" recited in claim 1, line 6 should be recited as "code" to provide for appropriate grammar. Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims have multiple antecedent basis issues. First, in claim 1, the phrases "said probes" in line 3 and "said molecule" in line 5 lack antecedent basis because the probes are recited as "single-stranded probes" and the molecules are recited as "encoded molecules." In other words, the above structures are recited generically after they are specifically labeled thus causing a lack of clarity.

Similar reasoning applies to the phrases "the nascent encoded molecule" recited in claim 3, "the nascent molecule" recited in claim 4, "the nucleic acid probe" and "the probe" recited in claim 7, "the nascent molecule" recited in claim 11, "the information" and "the nascent complex" recited in claim 12, and "the nucleic acid molecule" and "the array" and "the probe" recited in claims 15, 18, and 21.

Claim Rejections - 35 USC § 112 - New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation reciting, "encoded molecule is not a protein", added in Applicant's response dated June 3, 2008 was not contemplated in the disclosure at the time the application was filed, and thus, is new matter.

As understood by the examiner, Applicant points to page 1, line 26 to page 2, line 3 of the disclosure as providing support for this amendment; however, these portions are not considered to explicitly or inherently provide support for the above amendment because the disclosure does not expressly exclude "encoded molecules" from encompassing proteins. MPEP 2173.05 expressly recites, "Any negative limitation or exclusionary proviso must have basis in the original disclosure,..., The mere absence of a positive recitation is not basis for an exclusion." In other words, while the disclosure does positively recite presenting molecules other than proteins on the microarray, i.e.

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expanding from just proteins, the disclosure in no way presents an embodiment that expressly excludes proteins from the microarray. In fact, example 1 of the specification (pg. 22-32) recites the presentation of a library of tri-peptides, each of which can be considered a "protein" since there is no express definition of the term "protein" that requires such a molecule to be chemically active, i.e. the complete sequence of an active protein.

Claim Interpretation

Prior to application of prior art, the scope and content of the claimed invention must be analyzed. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim (see MPEP 2111.02, for example). In the instant case, for example, the phrase "which codes for said molecule" is considered an "intended use" of the product and is not interpreted as structurally limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-7 and 11-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Polsky-Cynkin et al. ("Use of DNA immobilized on plastic and agarose supports to detect DNA by sandwich hybridization" Clin Chem. 1985 Sep;31(9):1438-43).

With regard to claim 1, Polsky-Cynkin teaches a product comprising a plurality of single stranded nucleic acid probes immobilized in discrete areas of a solid support (*fig. 1, teaches solid phase with immobilized probes; pg. 1439, Solid Supports, teaches SPRs, polystyrene receptacles with immobilized DNA, for example*), said probes being hybridized to a library of complexes (*fig. 1, teaches complexes in hybridized form made of target DNA and labeled probe; pg. 1439, Hybridization, teaches hybridization of labeled A10 and B2 DNA fragments, for example*), wherein each complex comprises an encoded molecule and a template which codes for said molecule (*such a limitation is an intended use of the template molecules; that target DNA can be interpreted to "encode" for the labeled probe molecule, for example*), said template comprising a number of codons (*fig. 1, DNA nucleic acid bases can be interpreted as "codons", for example*) which codes for chemical entities which upon reaction form a reaction product which at least partly form part of the encoded molecule (*such language does not necessarily limit the claimed product because the "chemical entities" are not recited as a required structural component of the invention, i.e. the "chemical entities" are not recited as part of the "template" or "encoded molecule" of the "complexes"; all that is*

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required by the phrase is that the "codons" code for "chemical entities", which is an intended use of the "codons").

With regard to claims 2-5, 11-13, 16, and 19, the "chemical entities" are not recited as a required structural component of the claimed product (see discussion above).

With regard to claims 6, 14, 17, 20, 22, and 23, Polsky-Cynkin teaches DNA target with more than two nucleotide bases (fig. 1, for example).

With regard to claims 7, 15, 18, 21, and 24, if the radioactive label itself according the reference is interpreted as the "encoded molecule" then the target DNA can be interpreted as the "adapter molecule" (fig. 1, for example).

2. Claims 1-6, 11-14, 16, 17, 19, 20, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Szostak et al. (U.S. 6,207,446 B1).

With regard to claim 1, Szostak teaches a product comprising a plurality of single stranded nucleic acid probes immobilized in discrete areas of a solid support, said probes being hybridized to a library of complexes, wherein each complex comprises an encoded molecule and a template which codes for said molecule, said template comprising a number of codons (*col. 42-44, RNA-protein fusions in microchip format*) which codes for chemical entities which upon reaction form a reaction product which at least partly form part of the encoded molecule (*see discussion of language above*).

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With regard to claims 2-5, 11-13, 16, and 19, the "chemical entities" are not recited as a required structural component of the claimed product (see discussion above).

With regard to claims 6, 14, 17, and 20, Szostak teaches DNA target with more than two nucleotide bases (fig. 1, multiple amino acids from DNA triplets, for example).

With regard to claims 22 and 24, if the fluorescent label itself according the reference (col. 42, for example) is interpreted as the "encoded molecule" then such molecule is not a protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 15, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szostak et al. (U.S. 6,207,446 B1) in view of Felder et al. (U.S. 6,232,066 B1).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach hybridization to a solid support through an adapter oligonucleotide.

Felder teaches the use a microarray configuration that utilizes a linker oligonucleotide, i.e. an adaptor oligonucleotide, to attach target labeled mRNA molecules to the microarray (fig. 1,2; col. 3, for example). The references expressly teaches that the illustrated combination of anchor and linker oligonucleotides on the microarray configuration can allow the simultaneous detection of target mRNA from 15 different samples (col. 3, lines 40-50, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to utilize the microarray configuration according to Felder to detect the mRNA-protein fusion molecules according to Szostak since the prior suggests such a combination to allow for the simultaneous analysis of 15 different samples.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Dower et al. (U.S. 5,770,358). The reference teaches tagging a collection of pentapeptides with oligonucleotides (col. 26-29, example 2, for example).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner
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